REMARKS

Status of the Claims

Claims 1-2 and 4-8 remain pending and presented for examination.

General Comments regarding difference between Oils and Oil Bodies

At the outset applicants would emphasize again the differences separating oil bodies, as presently recited, from oil. This distinction warrants underscoring in no small part because the Advisory Action reflects not its apprehension but rather its dismissal, as mere "attorney arguments." Advisory Action, page 2.

Plant oils comprise triacylglycerides ("oil") exclusively, whereas plant oil bodies contain triacyclycerides ("oil"), protein, and phospholipids. Thus, an oil body is a three-dimensional structure in which the "oil" is packaged within a core ("oil core"), which is surrounded by a phospholipid and protein shell. See applicants' Response of May 2011, Exhibits A-C, as well as the specification, e.g., at paragraph [0006] of the published version. Without phospholipid and protein, therefore, oil bodies *per se* cannot exist.

Because of these significant structural and compositional differences, oil and oil bodies are extracted by different methods. To extract oil, harsh processes crush the oil body structure, thereby releasing oil from the oil core. Thus, the harsh extraction procedures cause the oil bodies actually to lose their structural integrity and, as such, to cease existence.

In obtaining an oil body, by contrast, one is careful *not* to crush or otherwise to compromise the oil-body structure. An oil body necessarily has an integral (non-broken) structure, therefore.

In summary, then, "oil" and "oil bodies" are not synonyms. Rather, they denote entities that are distinct, one from the other, in structure and appearance. This distinction goes to the heart of the definition of "oil bodies," and the record is replete with evidence on point. Accordingly, the distinction is not a matter of mere attorney argument.

Rejections under 35 U.S.C. § 112 (Indefiniteness)

Claim 7 stands rejected for alleged indefiniteness surrounding "emulsifier." Advisory Action, page 2. While acknowledging that the specification defines an emulsifier -- "an ingredient that can be used to bind or mix together two or more immiscible substances and prevent them from separating"), and admitting "a person of ordinary skill in the art would know the function of an emulsifier," the PTO alleges that it is unclear what the metes and bounds of the recited "emulsifier" should be." *Id.* Applicants respectfully traverse the grounds for this rejection.

The PTO is understood to take the position that a broad range of chemicals may have "some characteristic" of an emulsifier; hence, that a skilled person may disagree over what exactly constitutes an emulsifier. *Id.* In other words, the PTO seems to allege that that many a chemical could have emulsifier activity and yet may not be deemed an "emulsifier."

The PTO provides no example or other evidence, however, of a compound having "some characteristic" of an emulsifier that those in the field do not consider an emulsifier. The PTO must clearly articulate and provide technical rationale supporting why it doubts applicants' disclosure of their claimed invention. The absence here of such clear articulation and rational is sufficient reason alone for withdrawal of this Section 112 rejection.

The PTO seems to base its rejection on the perceived breadth or sheer number of available emulsifiers. Nevertheless, the PTO's rules expressly state that "[b]readth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, [as is the case presently,] and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph." MPEP § 2173.04.

Furthermore, the PTO rules and the Patent Statute make no requirement that an applicant disclose an exhaustive or even exemplary list of emulsifiers. In fact, the

Federal Circuit has routinely held that claims should not be limited to disclosed or even preferred embodiments. See, e.g., *Phillips v. AWH. Corp.* 415 F.3d 1303 at 1323 (Fed Cir. 2005) (*en banc*). Likewise, the Federal Circuit remains mindful "that the specification is the single best guide to the meaning of a disputed term." *Larryngeal Mask Company v. LMA North America* _ F.3d_ (Fed Cir. 2010).

Here, the application describes creating an emulsion without an external or additional emulsifier. As the specification explains, the "method of the present invention requires no additional emollients, emulsifiers etc. which constitutes a substantial advantage over the methods and products of prior art. In a preferred embodiment, no additional emulsifier is used." *Id.* at published paragraph [0022]. Furthermore, the specification discloses that safflower oleosomes were substitutes for conventional dilutents, emollients and emulsifiers known in the art. *Id.* at published paragraph [0034].

The specification thus leaves no doubt as to the meaning of "emulsifier." A person skilled in the art also would understand that the contemplated cosmetic product is an oil-in-water emulsion where an active ingredient is combined with an aqueous emulsion of washed, discrete spheres of vegetable oil bodies (oleosomes), and that the oil bodies function as an emulsifier.

Since the meaning of claim 7 is discernible, the rejection should be withdrawn.

Rejections under 35 U.S.C. § 102

A. Lorant (U.S. Patent No. 6,465,402)

Claims 1-4 remain rejected as allegedly anticipated by Lorant, U.S. Patent No. 6,465,402. Advisory Action, page 2. The PTO maintains its position that Lorant discloses a cold pressed oil, which inherently (*i.e.*, necessarily) comprises vegetable oil bodies. Applicants respectfully traverse this rejection.

In order to anticipate, a reference must disclose, either inherently or expressly, each and every element of the claim. MPEP § 2131. In the case of an allegedly inherent disclosure, the missing element must be necessarily present. "The fact that a certain

result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Inherency, however, may not be established by probabilities or possibilities." MPEP § 2112.

As explained previously, Lorant does not disclose, inherently or explicitly, a cosmetic comprising intact oil bodies. This is so because Lorant teaches oil, which is distinct from oil bodies, an *evidentiary* point highlighted above. That is, Lorant does not teach a three-dimensional structure in which "oil" is packaged within an "oil core," surrounded by a phospholipid and protein shell.

Yet, for reasons that remain unclear and that certainly are unstated, the examiner insists that Lorant comprises oil *bodies*. Nowhere does the record reflect any credible support for this allegation. For instance, the PTO does not cite any particular disclosure in Lorant that demonstrates the presence of oil bodies. Further, the PTO does not rely on any technical reference supporting its position that a cold pressed oil product necessarily comprises oil bodies.

Without such underpinnings, the PTO cannot satisfy its burden for establishing *prima facie* anticipation. For this reason, too, the rejection is improper and should be withdrawn.

Confronted with applicants' specific and technical comments on Lorant's emulsions, the PTO dismisses such remarks as "attorney arguments," alleging that applicants' technical comments are of "insufficient weight." Advisory Action, page 2. Shifting the burden, the PTO now requires that applicants "provide evidence that the cited prior art compositions do not contain said vegetable oil bodies." *Id.*

The PTO cannot shift or otherwise ignore its burden, however, particularly when the PTO has not provided any credible evidence or explanation of record that would cast doubt on applicants' technical comments, including those embodied in the original specification. Contrary to the examiner's stated position, nowhere do the PTO rules require applicants to marshal evidence when the PTO has not satisfied its initial burden.

Solely to advance prosecution, however, applicants have considered Lorant's oils and yet again proffer commentary on the point that Lorant's oils are not and do not include oil bodies. Lorant discloses cold pressed oils, such as sesame, macadamia, sunflower oils, and as known in the art, cold pressed oils lack protein. For example, commercial oil manufacturers Loriva and Brookfarms produce a variety of cold pressed oils, and these cold pressed oils lack protein. See Exhibits A-B, providing label ingredients and nutritional information of illustrative and publicly available cold pressed oils. Because, as can be seen on the labels in Exhibits A-B, the cold pressed oils do not contain protein, the oils do not contain oil bodies.

Again, while not required to refute the PTO's unsubstantiated position, applicants purchased cold pressed oils from several manufacturers, each of whom states that the oils lack protein. Specifically, applicants considered three oils: (1) Manitoba Harvest hemp oil (available from www.manitobaharvest.com), (2) Natur cold-pressed safflower oil (www.avogel.ca); and (3) Highwood Crossing flax oil (www.highwoodcrossing.com).

The three purchased oils were subjected to particle size analysis and microscopic visualization. Because oils lack particles, *i.e.*, oil bodies, the particle size analyzer could not detect the oils unless particles were created by sonication-mediated emulsification in water, thereby engendering enough dispersion of oil droplets for the particle sizer to detect an obscuration. Exhibit C displays particle size distribution for the three oils, compared with the particle size distribution for safflower oilbodies, and dispels any notion that oil and oil bodies are synonymous.

Furthermore, Lorant discloses Miglyol 810, 812, and 818 (Dynamit Nobel) as preferred vegetable oils, and the manufacturer indicates these oils are clear and soluble in hexane and ether. See Exhibit D: Miglyol Product Information Sheet. As explained previously, oil bodies are neither clear nor soluble in hexane or ether. In fact, Tzen, *et al.* (1997), describes a method whereby hexane is used to evaluate the intactness and integrity of plant oil bodies, showing that oil contained within an oil body is not extractable by hexane. Tzen, *et al.*, *J. Biochem* 121: 762-68 (1997) (abstract appended).

This provides further evidence that the Miglyol products, as used in Lorant, do not contain oil bodies.

In summary, Lorant's emulsions are formulated from plant oils; hence, they do not comprise oil bodies. For this reason alone, Lorant does not anticipate methodology requiring oil bodies. By the same token, the Section 102 rejection is improper and should be withdrawn.

B. Marketman and Kleinig

Claims 1, 5, and 7 remain rejected as allegedly anticipated by Marketman, www.marketmanila.com (published January 2005), as evidenced by Kleinig, *Planta* (1978). Advisory Action, page 2. Specifically, the PTO alleges that "Marketman discloses fresh coconut juice extracted from young coconuts in which the meal is still thin, opaque, soft and easily scrapped from the inside of the fruit (page 1, last paragraph) and Kleinig discloses that oleosomes are present in all plant tissues." *Id.*

Applicants respectfully traverse this rejection because neither reference teaches that coconut juice, which is not a plant tissue, contains oil bodies or oil. In fact, coconut juice contains little or no oil, let alone oil bodies. For this reason alone, the rejection is improper and should be withdrawn.

Marketman discloses a coconut juice drink made from scraped coconut meat. While coconut meat may comprise both fat and protein, coconut juice has essentially no fat. For example, see Coconut Research Center, www.coconutresearchcenter.org. Because coconut juice has no fat, the juice could not contain oil bodies, which inherently require oil droplets surrounded by protein and phospholipid.

Nevertheless, applicant purchased a young coconut per Marketman and isolated both the coconut juice and the meat for particle size analysis. As shown in Exhibit D, coconut juice has very few particles, and such particles do not resemble oil bodies. Thus, coconut juice does not contain oil bodies.

Furthermore, while Marketman may relay breaking a coconut and pouring (i.e. mixing) the juice into a glass, as well as scraping coconut meat and adding to the coconut water, such acts neither prepare nor produce an oil-in-water emulsion. As explained in the instant specification, an oil-in-water emulsion requires mixing a water and an oil phase so that there is no separation of the two phases. Marketman does not make an oil-in water emulsion.

In contrast, Marketman mixes coconut juice, a liquid containing no oil bodies, with solid coconut meat. In so doing, Applicants submit that large chunks of coconut surface to the top of the juice and do not disperse to create and emulsion. Thus, Marketman does not disclose an oil-in water emulsion.

Accordingly, Marketman as evidenced by Kleinig do not anticipate the present claims and the rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 6 and 8 stand ejected for alleged obviousness over Lorant, U.S. Patent No. 6,465,402, in view of Kauranen, WO 2004/082642. Advisory Action, page 2.

The PTO relies on Lorant as discussed above, alleging that Lorant discloses "an oil-in-water emulsion cream comprising vegetable oil, apricot oil and 77.6% water" but does not disclose the inclusion of safflower oil. To remedy this deficiency the PTO cites Kauranen for teaching (a) skin care products containing vegetable oils, such as safflower oil, and (b) "cold pressed" seed oils that would have contained vegetable oil oleosomes. *Id.* Applicants respectfully traverse the grounds for this rejection.

In order to validate a conclusion that a claim would have been obvious, the PTO must show that all recited elements of the claim were evidenced in the art. Further, the PTO must demonstrate that one of ordinary skill could have combined the elements in the manner claimed, via known methodology, with no change in the respective function(s) of the elements and with the resultant combination yielding nothing more than predictable results. *KSR v. Teleflex*, 127 S. Ct. 1727, 1739 (2007).

If any of these requirements does not pertain, then the PTO is barred from concluding that the claim in question would have been obvious. Such is the case here because neither Lorant nor Kauranen suggests oil bodies. Accordingly, neither reference nor any combination of them could have implicated methodology for preparing a cosmetic by using an aqueous emulsion of oil bodies.

As explained above, Lorant does not disclose methodology for preparing a cosmetic comprising an oil-in-water emulsion, by mixing at least one cosmetically or dermatologically active ingredient with an aqueous emulsion of washed, discrete spheres of vegetable oil bodies (oleosomes). Kauranen does not remedy Lorant's admitted deficiencies because Kauranen does not disclose oil bodies at all. That is, while Kauranen may disclose safflower oil, that oil does not comprise oil bodies, contrary to the PTO's stated opinion. Accordingly, no permissible permutation of Lorant and Kauranen could render the claims obvious, within the meaning of Section 103, and the rejection therefore should be withdrawn.

CONCLUSION

Applicants submit that the present claims are in allowable condition, and they request an early indication to this effect. Examiner Greene is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

Date December 5, 2011

By /Stephen A. Bent/

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Attorney for Applicants
Registration No. 29,768

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

EXHIBIT A

Nutritional Information for Safflower Cold Pressed Oil

Nutritional Facts

Serving Size: **1 Tbsp (14g)**

Serving Per Container: **25**

Calories:	Calories from Fat:
120	**120**

Total Fat: 14g

Saturated Fat: 1g

Trans Fat: 0g

Cholesterol: 0mg

Sodium: 0mg

Carbohydrates: 0g

Fiber: 0g

Sugars: 0g

Protein: 0g

Vitamin A: 0% • Vitamin C: 0%

Calcium: 0% • Iron: 0%

Source: www.loriva.com/products (December 2011)

EXHIBIT B

Nutrition Facts: Brookfarm Cold Pressed Macademia Oil
(source: www.brookfarm.com.au; December 2011)

- Serving size: 5ml
-

	Per 5ml	Per 100ml
Energy	173kj 41cal	3460kj 826cal
Protein	**0.0g**	**0.0g**
Carbohydrates	0.0g	0.0g
Fats total	5g	100g
saturated	0.7g	13.5g
trans	0g	0g
polyunsaturated	0.1g	2.5g
monounsaturated	4.2g	84.0g
Sodium	0mg	0mg
Cholesterol	0mg	0mg

EXHIBIT C

Particle Size Distribution of Oils Compared with Oilbodies

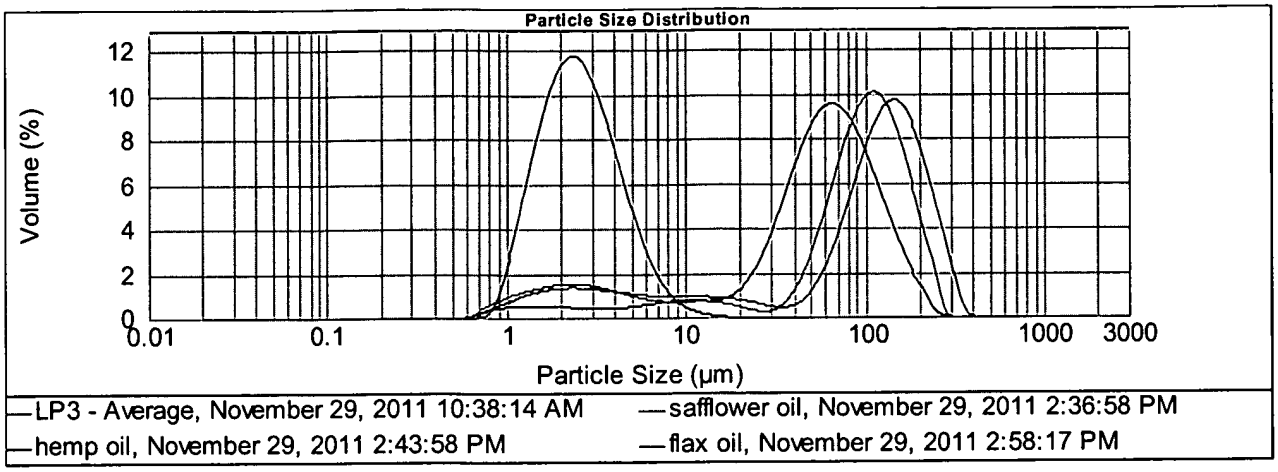

EXHIBIT D

Particle size analysis of young coconut juice

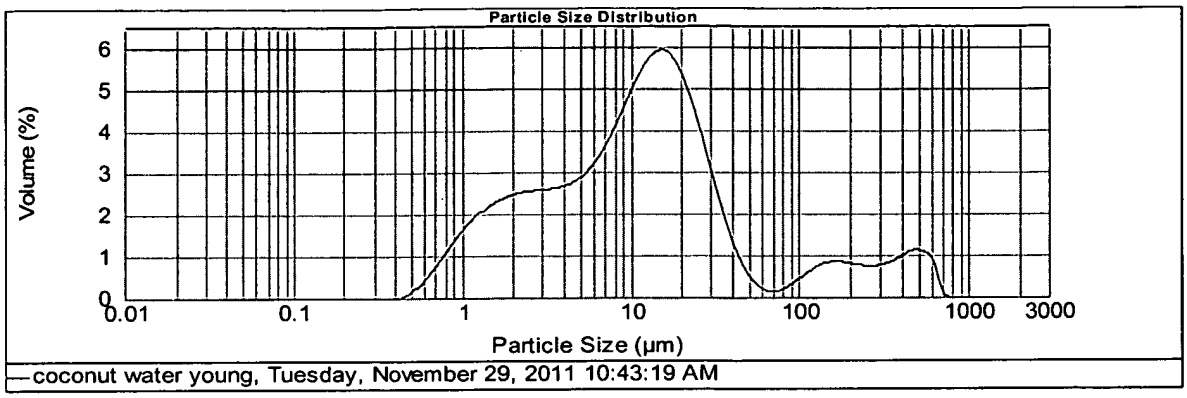

Exhibit E

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Product Information

09.04

MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

1. Description

MIGLYOL neutral oils are clear, slightly yellowish esters of saturated coconut and palmkernel oil-derived caprylic and capric fatty acids and glycerin or propylene glycol (MIGLYOL 840).

2. INCI (CTFA) and JCIC** names:

MIGLYOL 810, 812	Caprylic/Capric Triglyceride (JCIC: Caprylic/Capric Acid Triglyceride)
MIGLYOL 818	Caprylic/Capric/Linoleic Triglyceride
MIGLYOL 829	Caprylic/Capric/Succinic Triglyceride
MIGLYOL 840	Propylene Glycol Dicaprylate/Dicaprate

3. Properties

MIGLYOL neutral oils are clear, virtually colorless liquids of neutral odor and taste.

MIGLYOL neutral oils are very pure because of their carefully selected raw materials. As a result of tightly controlled manufacturing process, they contain very few microorganisms and are free of additives such as antioxidants, solvents and catalyst residues (Exception: MIGLYOL 818, which contains an antioxidant).

MIGLYOL neutral oils have the following advantages in comparison to natural oils:

High stability against oxidation (Exception: MIGLYOL 818 contains about 4 % linoleic acid).

Liquid at 0 °C.

Excellent spreadability on the skin and good skin absorption.

Do not inhibit skin-respiration.

Excellent penetration-promoting, emollient and skin-smoothing properties.

Very good solubility characteristics.

4. Solubilities

MIGLYOL neutral oils are soluble at 20 °C in the following solvents:
Hexane, toluene, diethyl ether, ethyl acetate, acetone, isopropanol, and ethanol 96%.
Neutral oils are miscible in all ratios with paraffin hydrocarbons and natural oils.

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Product Information

09.04

MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

Characteristic Values

Tests	810	812	818	829	840
Acid value (mg KOH/g) a)	max. 0.1	max. 0.1	max. 0.2	max. 1	max. 0.1
Iodine value (g I_2/100 g) b)	max. 0.5	max. 0.5	max. 10	max. 1 *	max. 0.5
Saponification value (mg KOH/g) c)	335 – 355	325 – 345	315 – 335	400 – 430	320 – 340
Peroxide value (mequi O/kg) d)	max. 1,0	max. 1,0	max. 5	max. 1 *	max. 1,0
Hydroxyl value (mg KOH/g) e)	max. 5	max. 5	max. 10	max. 15	max. 5
Colour (APHA) f)	max. 100	max. 100	max. 150	max. 200	max. 50
Water (%) g)	max. 0.1	max. 0.1	max. 0.1	max. 0.25 *	max. 0.1
Refractive index n^{20}_D h)	1.448 – 1.451	1.449 – 1.451	1.450 – 1.453	1.456 – 1.459	1.440 – 1.442
Density at 20 °C (g/cm³) i)	0.94 – 0.95	0.94 – 0.95	0.93 – 0.95	1.00 – 1.02 *	0.91 – 0.93
Viscosity at 20 °C (mPa·s) j)	27 – 33	27 – 33	30 – 35 *	ca. 230 – 270 *	9 – 12
Alkaline reactive substances k) (ml HCl/2 g)	max. 0.15	max. 0.15	max. 0.15 *	max. 0.15 *	max. 0.15
Heavy metals (ppm) l)	max. 10	max. 10	max. 10 *	max. 10 *	max. 10 *
Total ash (%) m)	max. 0.1	max. 0.1	max. 0.2 *	max. 0.2 *	max. 0.05
Unsaponifiable matter (%) n)	max. 0.3	max. 0.3 *	max. 0.3	max. 0.5 *	max. 0.3

Composition of fatty acids

Tests	810	812	818	829	840
Caproic acid ($C_{6:0}$)	max. 2,0	max. 2,0	max. 2 *	max. 2 *	max. 2 *
Caprylic acid ($C_{8:0}$)	65,0 – 80,0	50,0 – 65,0	45 – 65 *	45 – 55 *	65 – 80 *
Capric acid ($C_{10:0}$)	20,0 – 35,0	30,0 – 45,0	30 – 45 *	30 – 40 *	20 – 35 *
Lauric acid ($C_{12:0}$)	max. 2	max. 2	max. 3 *	max. 3 *	max. 2 *
Myristic acid ($C_{14:0}$)	max. 1,0	max. 1,0	max. 1 *	max. 1 *	max. 1 *
Linoleic acid ($C_{18:2}$)	-	-	2 – 5 *	-	-
Succinic acid	-	-	-	15 – 20 *	-

** not included in Certificate of Analysis, but checked randomly, limits guaranteed*

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Product Information

09.04

MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

5. Individual Descriptions

MIGLYOL 810/812

MIGLYOL 810/812 are triglycerides of the fractionated plant fatty acids C_8 and C_{10}. They meet the requirements of the following monographs:

Ph.Eur. (Edition 4.6)	- Medium Chain Triglycerides
USP / NF 22	- Medium - Chain Triglycerides
BP 1999**	- Fractionated Coconut Oil
JPE **	- Caprylic/Capric Triglyceride

MIGLYOL 810/812 differ only in C_8/C_{10}-ratio. Because of its low C_{10}-content, the viscosity and cloud point of MIGLYOL 810 is lower.
The fatty acids used for the production of MIGLYOL 810/812 comply with CFR** 21, § 172.860 and are classified as GRAS**. CAS-No. 73 398-61-5.

MIGLYOL 818

MIGLYOL 818 is a triglyceride of the fractionated plant fatty acids C_8 und C_{10} and contains about 4 to 5 % linoleic acid.
For physiological nutrition and special skin effects, triglycerides with a defined amount of double unsaturated fatty acids are used in pharmaceuticals and cosmetics. CAS-No. 67 701-28-4.

MIGLYOL 829

MIGLYOL 829 is a glycerin ester of the fractionated plant fatty acids C_8 und C_{10}, combined with succinic acid. The viscosity is about 230 mPa·s.
Because of its high density of 1.00 – 1.02 g/cm³ MIGLYOL 829 promotes stability in emulsions. According to CFR 21, § 172.830 (succinylated monoglycerides) special succinic esters of fatty acid glycerides are recognized as safe (GRAS). CAS-No. 91744-56-8. DMF no.: 10495.

MIGLYOL 840

MIGLYOL 840 is a propylene glycol diester of saturated plant fatty acids with chain lengths of C_8 and C_{10}. Therefore it has excellent emollient properties.
The very low viscosity of MIGLYOL 840 makes it suitable as a carrier oil for i.m.-injection preparations.
It meets the requirements of the following monographs:

DAB **	- Propylenglycoloctanoatdecanoat
JCIC**	- Propylene Glycol Dicaprylate/Dicaprate

Propylene glycol esters of edible fatty acids in food comply with CFR 21, § 172.856 and are classified as GRAS. CAS-No. 68 583-51-7.

Product Information

09.04

MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

6. Applications

Pharmaceuticals

Oral Products

Tablets, dragees:	Anti-sticking, polishing agents.
Soft gelatine capsules:	Chemically neutral, low-viscosity carrier oil, absorption promoter.
Drops:	Carrier, solvent, and absorption promoter.
Suspensions, syrups:	Carrier and absorption promoter for antibiotics etc.
Aerosol products:	Carrier and solvent (nitroglycerine etc..).

Parenteral Products

Intravenous infusions:	MIGLYOL 810 and 812 as part of fatty emulsions for parenteral nutrition.
Intramuscular injections:	Carrier and solvent.
Intramammary injections:	Carrier and solvent.

Topical theraputics

Psoriasis Treatment and Antiprucitics:	Readily absorbent, scale-detaching and keratin-softening oil component, particularly in combination with Vitamin A.
Ointments:	Non-oxidizing, absorption-promoting, non-occlusive oil component with excellent spreadability.

Rectal products

Anti-nucleating and dispersing aid for active ingredients in Hard Fat (WITEPSOL)-suppositories.

Dietetic products/Nutraceuticals

Medium chain triglycerides (MCT) differ from natural fats (LCT) with regard to these essential properties:

Quick metalbolism, not stored as body fat.
Physiological caloric value = 8,2 kcal/g (34,3 kJ/g) compared with LCT = 9,2 kcal/g (38,5 kJ/g).
Different absorption and metabolism properties: MCT are partially utilized if fat resportion disorders exit.

Cosmetic

Skin care cosmetics

Creams and lotions:	Non-greasy emollient oil components with very good spreadability.

Product Information
09.04

MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

Compared with petrolatum and mineral oil:	They are skin-permeable, do not obstruct natural skin respiration.
Skin, face and baby oils:	Non-oxidizing, penetration-enhancing lipid bases.
Massage oils:	Low-viscosity oil bases with excellent spreadability.
Masks:	Emollient skin care additives.

Decorative Cosmetic

Make-Up, sticks, mascara:	Dispersing oil component, compatible with pigments.
Makeup remover:	MIGLYOL disperses pigments and acts as a solubilizer.

Cleansing cosmetics

Two-phase foam baths:	Fat component, readily miscible with natural oils and surfactants.

Sunscreens

O/W sunscreen creams:	Oil component, compatible with organic and inorganic filter agents.
W/O sunscreen creams, sunscreen oils:	Water-resistant oil components, less greasy, do not obstruct skin respiration.

Perfumes

Fixative for fragrances

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7. Toxicological data

Caprylic/Capric triglycerides comply with Safety Assessment, of „The expert panel of the cosmetic ingredient review" and are classified as safe (JEPT** 4 (4), 1980).

Skin compatibility

Primary skin compatibility test (Draize-Skin-test):	MIGLYOL 829: Irritation index 0.5 (mild irritant).
All other MIGLYOL neutral oils:	Irritation index 0 (non-irritant).
Percutanous Patch-Test:	No irritation to healthy and eczematous skin.
Sensibilization test (Contact Sensitization-test):	No contact allergenicity.

Mucosal compatibility

Draize-Eye-Test: No irritation of cornea or iris with MIGLYOL 810, 812, 829 and 840.

Product Information
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MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

Oral Tolerance

Acute oral toxicity (LD_{50}): For all MIGLYOL neutral oils more than 5 g/kg body weight.

Parenteral Tolerance

Acute intraperitoneal toxicity:

MIGLYOL 812: i.p. LD_{50} (mouse)		> 2 g/kg
MIGLYOL 812: i.p. LD_{50} (rat)		> 8 g/kg
MIGLYOL 829: i.p. LD_{50} (rat, mouse)		> 5 g/kg
Intramuscular toxicity:	MIGLYOL 812, 840:	No histopathological results.
Acute inhalation toxicity:	MIGLYOL 812, 829, 840:	No histopathological results.

Environmental tolerance

MIGLYOL neutral oils are readily biodegradable. Therefore they have the same behaviour as natural fat products with a triglyceride structure.

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8. Packaging instructions

MIGLYOL neutral oils are good solvents, like other low-viscosity polar ester oils. Some plastics, especially those containing plastisizers, can become brittle or expand. Polystyrene and PVC are not suitable.

Be careful when selecting resistant-seal closure material (e.g., VITON), and be careful of sufficient pull power because MIGLYOL neutral oils have a high tendency to migrate.

The following packaging materials are recommended:

- Low pressure polyethylene (High Density PE = HDPE)
- Polypropylene
- Metal (aluminium)
- Glass

Product Information

09.04

MIGLYOL® 810, 812, 818, 829, 840 Neutral Oils For Pharmaceuticals and Cosmetics

9. Packaging

Plastic multitainers of 25 kg net
Steel drums with an inner lacquer lining of 190 kg net
Totes of 950 kg net
Road tankers

10. Storage and Shelf Life

MIGLYOL neutral oils are not heat-sensitive. Even in hot climates cooling is not necessary. At low temperatures parts of the triglycerides may crystallize. This phenomenon is completely reversible.

MIGLYOL neutral oils have a very low water content, and are therefore not sensitive to hydrolytic and microbial splitting. If stored in tightly closed containers, protected from moisture and light, the shelf life for MIGLYOL types 810, 812, 829 and 840 (see package guidelines) is at least 3 years, for MIGLYOL 818 one year.

11. Methods

a) Ph.Eur. 2.5.1, b) Ph.Eur. 2.5.4, c) Ph.Eur. 2.5.6, d) Ph.Eur. 2.5.5, e) Ph.Eur. 2.5.3, f) APHA, g) Ph.Eur. 2.5.12, h) Ph.Eur. 2.2.6, i) Ph.Eur. 2.2.5, j) Ph.Eur. 2.2.8, k) Ph.Eur. 2.4.19, l) Ph.Eur. 2.4.8, method D, m) Ph.Eur. 2.4.16, n) Ph.Eur. 2.5.7

** *JCIC = Japanese Cosmetic Ingredients Codex*

** *BP Add = British Pharmacopoeia*

** *CFR = Code of Federal Regulations*

** *DAB = Deutsches Arzneibuch*

** *GRAS = Generally Recognized As Safe*

** *JEPT = Journal of Environmental Pathology and Toxicology*

** *JPE = Japanese Pharmaceutical Excipients*

** *DMF = Drug Master File*

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Abstract

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A New Method for Seed Oil Body Purification and Examination of Oil Body Integrity Following Germination[1]

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Abstract

Plant seeds store triacylglycerols as energy sources for germination and postgerminative growth of seedlings. The triacylglycerols are preserved in small, discrete, intracellular organelles called oil bodies. A new method was developed to purify seed oil bodies. The method included extraction, flotation by centrifugation, detergent washing, ionic elution, treatment with a chaotropic agent, and integrity testing by use of hexane. These processes subsequently removed non-specifically associated or trapped proteins within the oil bodies. Oil bodies purified by this method maintained their integrity and displayed electrostatic repulsion and steric hindrance on their surface. Compared with the previous procedure, this method allowed higher purification of oil bodies, as demonstrated by SDS-PAGE using five species of oilseeds. Oil bodies purified from sesame were further analyzed by two-dimensional gel electrophoresis and revealed two potential oleosin isoforms. The integrity of oil bodies in germinating sesame seedlings was examined by hexane extraction. Our results indicated that consumption of triacylglycerols reduced gradually the total amount of oil bodies in seedlings, whereas no alteration was observed in the integrity of remaining oil bodies. This observation implies that oil bodies in germinating seeds are not degraded simultaneously. It is suggested that glyoxisomes, with the assistance of mitochondria, fuse and digest oil bodies one at a time, while the remaining oil bodies are preserved intact during the whole period of germination.

Key words oil body oleosin organelle integrity purification sesame

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